

REMARKS

Reconsideration of this application and withdrawal of the rejections set forth in the Office Action made final mailed March 4, 2010, is requested in view of this amendment and the following remarks. A Request for Continued Examination is being filed concurrently with this paper, thereby removing the finality of the outstanding Office Action. Claims 1-15, 17-19, 21-27, and 36-37 were pending and at issue prior to this amendment. Claims 1, 15, 17, 18, 21, 22, 23, 36 and 37 have been amended herein. The claims as amended are fully supported by the original specification as filed.

I. Claim Objections

Claims 17, 18 and 21-23 were objected to because they depend from canceled claims. Claims 17, 18 and 21-23 have been amended herein to depend from currently pending claims. Specifically, claims 17 and 18 have been amended to depend from claim 15, and claims 21-23 have been amended to depend from claim 19. This is also consistent with the assumption made by the Examiner in examining these claims. Accordingly, this objection should be withdrawn.

II. Rejection of Claim 36 under 35 U.S.C. Section 112, first paragraph

Claim 36 stands rejected under 35 U.S.C. Section 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that the specification fails to support the limitation in claim 36 reciting a marker wire having a first and a second end offset from each other in a circumferential direction and along the length of the medical device in combination with the first and second directional indicators that connect in an image to form a symbol when viewed in the proper rotation. Applicant respectfully submits that Fig. 9 indeed shows a marker wire having a first and second end offset from each other circumferentially and along the length of the device, in combination with the first and second directional indicators.

Any three of the segments making up the closed shape comprise a marker wire having a first and second end offset from each other circumferentially and along the length of the device. Clearly, this is in combination with the first and second directional indicators.

Thus, claim 36 is supported in the specification as filed, and this rejection should be withdrawn.

III. Rejections under 35 U.S.C. Section 103(a)

Claims 1-7, 12, 15, 18, 19, 23-25 and 37

In the Office Action, the Examiner rejected claims 1-7, 12, 15, 18, 19, 23-25 and 37 under 35 U.S.C. Section 103(a) as being obvious over Makower '875 (U.S. Patent No. 6,302,875). Applicant respectfully submits that this rejection should be withdrawn because Makower '875 does not disclose , suggest or otherwise render obvious the claimed apparatus comprising a medical device comprising, *inter alia*, a first directional indicator coupled to said medical device, the first directional indicator comprising a first portion of a symbol; a second directional indicator coupled to said medical device offset from said first directional indicator, the second directional indicator comprising a second portion of the symbol; wherein images of said first and second directional indicators connect to form the symbol when viewed from a proper rotational orientation about the longitudinal axis when viewed orthogonally to the longitudinal axis using an imaging device.

While the Supreme Court in *KSR International Co. v. Teleflex Inc.* ("KSR")¹ held that there are no rigid rules for determining obviousness, the Court reaffirmed that "rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinnings to support the legal conclusion of

obviousness.² As reiterated by the Supreme Court in KSR, the framework for the objective analysis for determining obviousness under 35 U.S.C. §103 is stated in *Graham v. John Deere Co.*³ Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

- (1) Determining the scope and content of the prior art;
- (2) Ascertaining the differences between the claimed invention and the prior art; and
- (3) Resolving the level of ordinary skill in the pertinent art; and
- (4) Considering objective evidence (secondary considerations) indicating obviousness or non-obviousness.

Although the Court in KSR rejected rigid preventative rules in making an obviousness inquiry, the Court reaffirmed that there must be some articulated rationale in order to modify or combine the teachings of multiple references in making an obviousness rejection.⁴ Furthermore, the combined teachings of the prior art must at least result in the Applicant's claimed invention.

Therefore, to establish a *prima facie* case of obviousness, the Examiner must establish three basic criteria: first, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; second, there must be a reasonable expectation of success; and finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Moreover, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). It is

¹ 550 U.S. ___, ___ (2007)

² 550 U.S. ___, ___ (2007)

³ 550 U.S. ___, ___ (2007)

improper to pick and choose among features and elements found in the prior art references in a hindsight reconstruction of Applicants' claimed invention. *See e.g., In re Jones*, 958 F.2d 347, 350-51 (Fed. Cir. 1992); *In re Fritch*, 919 F.2d 720 (Fed Cir. 1990) ("It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious"). Furthermore, it is improper to combine the teachings of references where the references teach away from the asserted combination. MPEP § 2145. Applicant submits that the Examiner's obviousness rejection cannot be sustained consistent with these well-established requirements for obviousness.

The Examiner asserts that Makower '875 discloses two symbols that connect when viewed from a proper rotational orientation, but concedes that this is ONLY true when the taking "an image from an angle" to the longitudinal axis of the medical device. (See Office Action, para. 2). First of all, there is absolutely no teaching or suggestion in Makower '875 to image the markers at an angle such that the marker will connect to form a combined symbol. Thus, there is no teaching or suggestion in Makower '875 that would motivate one of ordinary skill in the art to design the markers to connect.

Furthermore, as the Examiner concedes, the markers of Makower '875 will not connect when viewed orthogonally to the longitudinal axis, as required by Applicants' claimed invention as amended herein. In fact, this is the way that Makower '875 teaches to use the device of Makower '875, as shown in the views of Fig. 6b other than the perspective view.

Moreover, if viewed at an angle, as suggested by the Examiner, the markers are much more difficult to align to obtain the desired rotational orientation because the markers become distorted when viewed at an angle. For example, the circle shaped marker of Makower '875

⁴ 550 U.S. __, __ (2007)

becomes an ellipse, and it is then difficult to visually gauge whether the dot shaped marker is in the center of the circle when viewed from an angle. Accordingly, Makower '875 would not suggest to one of ordinary skill in the art to modify the device of Makower '875 to produce Applicant's claimed invention comprising first and second directional indicators which connect to form a symbol when viewed from the proper rotational orientation.

As discussed in the Applicants' previous response, the connection of the markers is a significant and critical distinction, because the "connecting" images can provide for a much easier to read and accurate indicator. Similarly, the alignment of one marker within another marker does not provide for an indicator that is as easy to read and accurate as the indicator of Applicant's claimed invention. For example, the dot of the device of Figure 6b of Makower '875 may appear to be in the center of the circle but actually be slightly misaligned, and the lines of the markers of Fig. 6a may be slightly misaligned, but still appear be aligned because the ends of the lines are separated by a distance.

Therefore, claims 1-6, 13, 24, 25 and 37 are not obvious over Makower '875, and this rejection should be withdrawn.

Claim 17

Claim 17 stands rejected under 35 U.S.C. Section 103(a) as being obvious over Makower '875 in view of Nash (U.S. Publication No. 2002/0032432). This rejection should be withdrawn for at least the same reasons as the obviousness rejection over Makower '875, i.e., Nash does not overcome the deficiencies of Makower '875, as described above. Nash fails to disclose, suggest or otherwise render obvious an apparatus having first and second directional indicators wherein the images of the indicators connect to form the symbol when viewed from a proper rotational orientation using an imaging device. The markers of Makower '875 do not

connect to form a symbol when viewed from the proper rotational orientation about the longitudinal axis when viewed orthogonally to the longitudinal axis.

Accordingly, claim 17 is not obvious over Makower '875 in view of Nash, and this rejection should be withdrawn.

Claim 21

Claims 21 stands rejected under 35 U.S.C. Section 103(a) as being obvious over Makower '875 in view of Makower '311 (U.S. Patent No. 6,579,311). This rejection should be withdrawn for at least the same reasons as the obviousness rejection over Makower '875, i.e., neither Makower '875 nor Makower '311 disclose, suggest or otherwise render obvious an apparatus having first and second directional indicators wherein the images of the indicators connect to form the symbol when viewed from a proper rotational orientation about the longitudinal axis when viewed orthogonally to the longitudinal axis using an imaging device.

Although Makower '311 appears to disclose a marker which can be used to determine the rotational orientation of a medical device using an imaging device, it does not disclose the Applicant's claimed first and second directional indicators wherein the images of the indicators connect to form the image of a symbol when positioned in the proper rotational orientation. Instead, the marker of Makower '311 forms in image of a solid circle concentrically aligned with an open circle. As a result, the images of the marker of Makower '311 do NOT "connect" as required by Applicant's claimed first and second directional indicators. This is a significant and critical distinction, because the "connecting" images can provide for a much easier to read and accurate indicator. Similarly, the alignment of overlapping lines such as in Figs. 3a and 3b of Makower '311 does not provide for the easy to read and accurate indicator of Applicant's claimed invention. For example, the lines of the markers of Figs. 3a and 3b may be slightly

misaligned, but would still appear as a single, solid line. Furthermore, the use of simple lines are NOT a “symbol” as required by Applicant’s claimed invention. A symbol is much less susceptible to being confused with image artifacts than simple lines.

The markers of Makower ‘875 and Makower ‘311 do not connect to form a symbol when viewed from the proper rotational orientation about the longitudinal axis when viewed orthogonally to the longitudinal axis. Accordingly, claim 21 is not obvious over Makower ‘875 in view of Makower ‘311, and this rejection should be withdrawn.

Claim 36

Claim 36 stands rejected under 35 U.S.C. Section 103(a) as being obvious over Makower ‘875 in view of Makower ‘311. This rejection should be withdrawn for at least the same reasons as the obviousness rejection of claim 21 described above.

Accordingly, claim 36 is not obvious over Makower ‘875 in view of Makower ‘311, and this rejection should be withdrawn.

Claims 1-6, 13, 24, 25 and 37

Claims 1-6, 13, 24, 25 and 37 stands rejected under 35 U.S.C. Section 103(a) as being obvious over Makower ‘311 in view of Makower ‘875. This rejection should be withdrawn for at least the same reasons as the obviousness rejection of claims 21 and 36 described above.

Accordingly, claims 1-6, 13, 24, 25 and 37 are not obvious over Makower ‘311 in view of Makower ‘875, and this rejection should be withdrawn.

Claim 27

Claim 27 stands rejected under 35 U.S.C. Section 103(a) as being obvious over Makower ‘311 in view of Makower ‘875 and further in view of Plaia (U.S. Patent No. 6,497,711). This rejection should be withdrawn for at least the same reasons as the obviousness rejection of

claims 1, 21 and 36, described above because Plaia does not overcome the deficiencies of Makower '311 and Makower '875, as described above. Specifically, Plaia does not disclose, suggest or otherwise render obvious an apparatus having first and second directional indicators wherein the images of the indicators connect to form the symbol when viewed from a proper rotational orientation about the longitudinal axis when viewed orthogonally to the longitudinal axis using an imaging device.

Accordingly, claim 27 is not obvious over Makower '311 in view of Makower '875 and Plaia, and this rejection should be withdrawn.

Claims 1-6 and 24-26

Claims 1-6 and 24-26 stand rejected under 35 U.S.C. Section 103(a) as being obvious over Flaherty (U.S. Patent No. 6,660,024) in view of Makower '875. This rejection should be withdrawn for at least the same reasons as the obviousness rejections over Makower '875 in view of Makower '311, and the rejection over Makower '875, i.e., Flaherty does not overcome the deficiencies of Makower '875, as described above. Flaherty fails to disclose, suggest or otherwise render obvious an apparatus having first and second directional indicators wherein the images of the indicators connect to form the symbol when viewed from a proper rotational orientation about the longitudinal axis when viewed orthogonally to the longitudinal axis using an imaging device.

Accordingly, claims 1-6 and 24-26 are not obvious over Flaherty in view of Makower '875, and this rejection should be withdrawn.

Claim 27

Claim 27 stands rejected under 35 U.S.C. Section 103(a) as being obvious over Flaherty in view of Makower '875 and further in view of Plaia. This rejection should be withdrawn for at

least the same reasons as the obviousness rejection of claims 1, 21 and 36, described above because neither Flaherty nor Plaia overcome the deficiencies of Makower '311 and Makower '875, as described above. Specifically, Plaia and Flaherty do not disclose, suggest or otherwise render obvious an apparatus having first and second directional indicators wherein the images of the indicators connect to form the symbol when viewed from a proper rotational orientation about the longitudinal axis when viewed orthogonally to the longitudinal axis using an imaging device.

Accordingly, claim 27 is not obvious over Flaherty in view of Makower '875 and further in view of Plaia, and this rejection should be withdrawn.

Claims 1-5, 8-11 and 14

Claims 1-5, 8-11 and 14 stand rejected under 35 U.S.C. Section 103(a) as being obvious over Lombardi (U.S. Patent No. 5,824,042) in view of Makower '875. This rejection should be withdrawn for at least the same reasons as the obviousness rejection of claims 1, 21 and 36, described above because Lombardi does not overcome the deficiencies of Makower '311 and Makower '875, as described above. Specifically, Lombardi does not disclose, suggest or otherwise render obvious an apparatus having first and second directional indicators wherein the images of the indicators connect to form the symbol when viewed from a proper rotational orientation about the longitudinal axis when viewed orthogonally to the longitudinal axis using an imaging device.

Accordingly, claims 1-5, 8-11 and 14 are not obvious over Lombardi in view of Makower '875, and this rejection should be withdrawn.

Claims 15, 19, and 22

Claims 15, 19 and 22 stand rejected under 35 U.S.C. Section 103(a) as being obvious

over Armstrong (U.S. Publication No. 2002/0099431) in view of Makower '875. This rejection should be withdrawn for at least the same reasons as the obviousness rejection of claims 1, 21 and 36, described above because Armstrong does not overcome the deficiencies of Makower '311 and Makower '875, as described above. Specifically, Armstrong does not disclose, suggest or otherwise render obvious an apparatus having first and second directional indicators wherein the images of the indicators connect to form the symbol when viewed from a proper rotational orientation about the longitudinal axis when viewed orthogonally to the longitudinal axis using an imaging device.

Accordingly, claims 15, 19 and 22 are not obvious over Armstrong in view of Makower '875, and this rejection should be withdrawn.

Conclusion

Any claim amendments which are not specifically discussed in the above remarks are not made for reasons of patentability, do not affect the scope of the claims, and it is respectfully submitted that the claims satisfy the statutory requirements for patentability without the entry of such amendments. These amendments have only been made to increase claim readability, to improve grammar, or to reduce the time and effort required of those in the art to clearly understand the scope of the claim language.

In view of the foregoing remarks, Applicant respectfully submits that all of the Examiner's rejections have been overcome. Accordingly, allowance is earnestly solicited. If the Examiner feels that a telephone interview could expedite resolution of any remaining issues, the Examiner is encouraged to contact Applicant's undersigned representative at the phone number listed below.

Respectfully submitted,

Dated: June 2, 2010

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